



# How to manage research data ethically?

## Outline

### How to manage research data ethically?

- Ethics in research
- Key principles and best practices
- Legislation: Acts of the University of Bern and Canton of Bern
- IT-Security
- Ethics Committees
- Where to start and when? Workflow.

### Ethical aspects in data management plans



### Support References Q & A



# Ethics in research

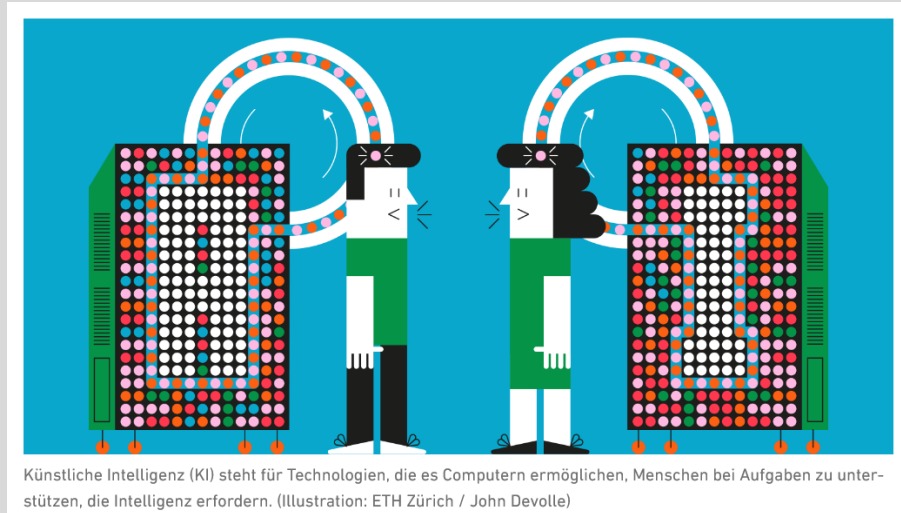
## Research on and with humans



# Ethics in research

## App-based research

### Research on and with mobile devices



# Ethics in research

## Personal and health-related data

### Personal data

- Any data that can be related to a person.

### Highly sensitive personal data

- Health, intimate sphere, “race”
- Religious, ideological, political or trade-union related views or activities
- Social security measures
- Administrative or criminal proceedings and sanctions.

### Personality Profile

- A collection of data that permits an assessment of essential characteristics of the personality of a natural person.

Ref. [Act on Data Protection of the Canton of Bern](#) (KDSG), Art. 2.

For informational purposes in English: [Federal Act on Data Protection](#), Art. 3a, c, d.

Other countries, e.g., Europe ([GDPR](#))

# Ethics in research

## Human health and safety, geodata

### Human health and safety



### Geodata: Federal Act on Geoinformation



# Ethics in research

## Research on and with plants



Federal Office for the Environment [FOEN](#)  
Red Lists: Threatened species in Switzerland



### Research Commission of the Swiss National Park (FOK-SNP)

FOK-SNP promotes and coordinates research projects in the Swiss National Park, in the Regional Nature Park Val Müstair and in the conservation and development zone of the Engiadina Val Müstair Biosphere Reserve. [more](#)

Image: Meisterfoto, stock.adobe.com

Research Commission of Swiss National Parks ([FOK-SNP](#))

# Ethics in research

## Nuclear energy and radioactive waste

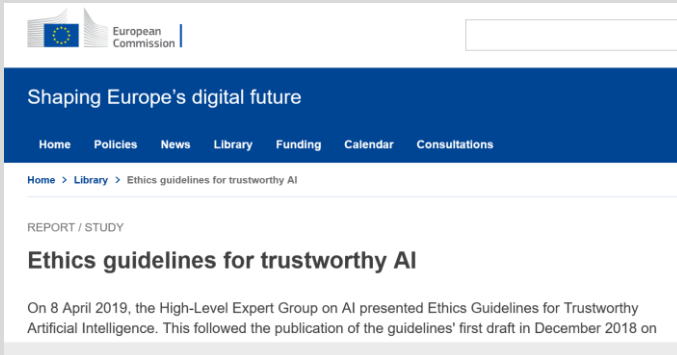


Nuclear Energy Ordinance ([Act](#))



# Ethics in research

## Artificial Intelligence (AI): key requirements



[Link](#)

### 7 key requirements that AI systems should meet:

- Empower human beings
- Be resilient and secure
- Ensure full respect for privacy and data protection
- Transparency
- Diversity, non-discrimination and fairness
- Societal and environmental well-being
- Accountability

# Ethics in research

## Key principles and best practices



# Ethics in research

## Good research practice

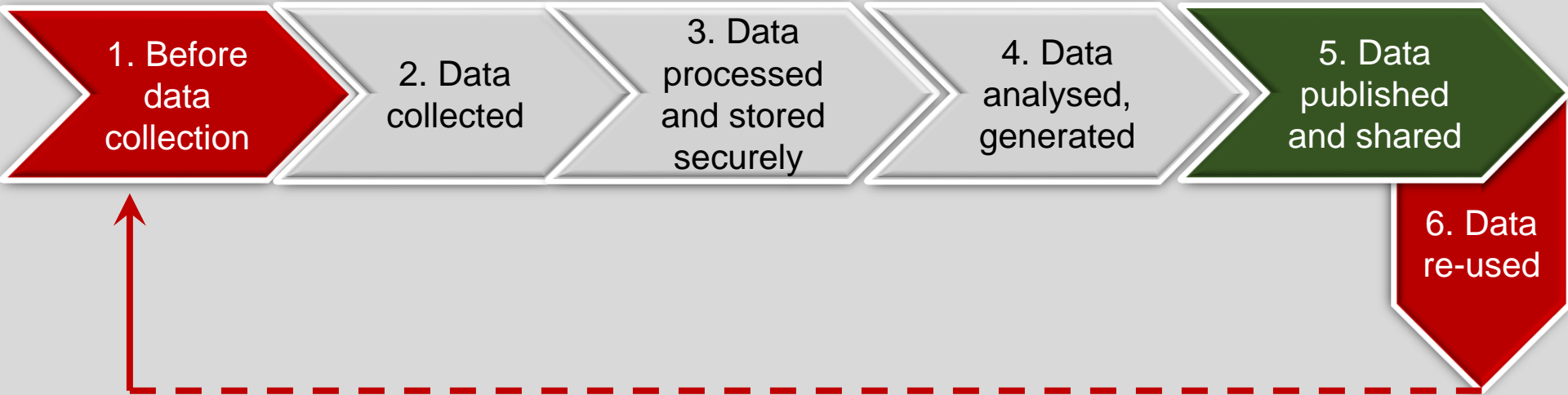


- Responsibility
- Ethical decision making
- Value basis
- Openness, where possible
- Reproducibility
- Traceability

# How to manage research data ethically

## Where and how to start?

### Data management phases



# How to manage research data ethically


## Data management phases

### 1. Before data collection

- Type of data collection
- [Data Protection Office of the Canton of Bern](#), [IT-Service Office](#), [Bern University Legal Services Office](#), Recht & Compliance Inselspital ([E-Mail](#))  
Third parties, partners included for data exchange, sharing conditions, agreements for data use or use of generated data
- Cantonal and faculty ethics committees, research councils & commissions
- Informed Consent (IC): If the documents are not in English, they must be submitted together with English summary (e.g., EU Projects)
- Clarify if IT setup complies with legal requirements (ISDS analysis → [support at UniBE](#))

# How to manage research data ethically

## Data management phases



### 2. Data collected

- Collect only data needed to fulfill the purpose of the study  
Principle of Proportionality is one of the [general principles of EU law](#), data minimisation
- Describe all data which should be collected in the Informed Consent



# How to manage research data ethically

## Data management phases

### 3. Data processed and stored securely



Secure storage space  
e.g., locked room

Archiving 10-15 years



### Anonymization tools

<https://arx.deidentifier.org/anonymization-tool/>

<https://amnesia.openaire.eu/>

# How to manage research data ethically

## Data management phases

4. Data  
analysed,  
generated



Data analysis and data generation

Data security

[Where and how to store?](#)

Data transfer

- IT security
- Appropriate databases

# How to manage research data ethically

## Data management phases

5. Data  
published  
and shared

**BORIS Portal**  
Research data,  
projects & fundings



[SNSF Check list](#) repositories

# How to manage research data ethically

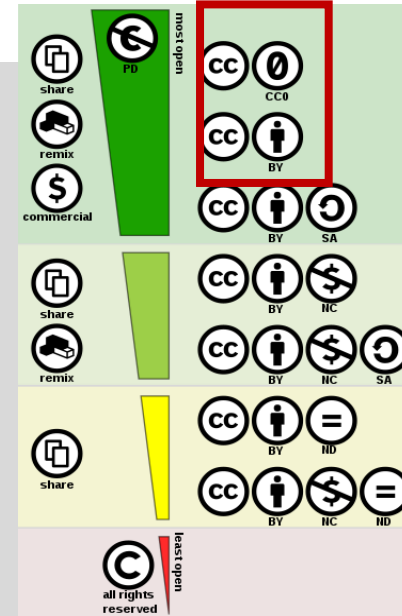
## Data management phases

### 1. Before data collection

#### To reuse data, take into account:

- Licences
- Ownership
- Data transfer agreements
- Written Joint Ownership Agreement (JOA)

CC0, CC-BY for anonymised data only!



### 6. Data re-used

# Ethics in research data management planning

Weeks (W) before the Swiss National Science Foundation (SNSF) project submission deadline

24 W

23 W

8 W

Legal aspects

Ethics

DMP review

- Legal office UniBE [E-Mail](#)
- UniTectra [E-Mail](#)
- Inselspital [E-Mail](#)
- ISDS questions [E-Mail](#)
- Data sharing / Transfer agreements / Ownership
- IT-Service at the UniBE ([E-Mail](#)), Faculty/ Institute/ Department

2 W

Feedback

Clinical studies which are not covered by Human Research Act ([HRA](#)) → Ethics commission

- [Phil.-hum.](#)
- [Wirtschafts- und Sozialwissensch.](#)
- Vetsuisse [Animal Welfare Office UniBE](#)

If clinical studies are covered by [HRA Ethics Commission of the Canton of Bern \(in German only\)](#), [Swissmedic](#)

3-8 W

- University library UniBE & Open Science Team [DMP Writing Lab](#)
- DMP [online](#) review or [e-mail](#)
- BORIS Portal: Research Data, Projects & Fundings

1 W

Feedback

# Ethics in research data management

## EU-Commission requirements

### ✓ Dos

- Proportionality (gender, equal opportunities)
- Right to privacy
- Right to protection of personal data
- Right to the physical and mental integrity of persons
- The right to non-discrimination
- The need to ensure protection of the environment
- High levels of human health protection

### x Don'ts

- Human cloning for reproductive purpose
- Intend to modify the genetic heritage of human beings (except cancer research)
- Intend to create human embryos solely for the purpose of research or stem cell procurement
- Lead to the destruction of study subject



# Ethics in research data management

## Sensitive information and security (EU projects)

### Before starting the action task:

Obtain all approvals (national or local ethics committees), data protection authorities or other mandatory documents needed

- If the documents are not in English, they must be submitted together with English summary
- **Restricted access** – info can be disseminated only after written approval from the granting authority ([AMGA](#) v.1 01.06.21)



**No funding can be granted** within or outside the EU, for activities that **are prohibited in all member states.**

**No funding can be granted** in a member state for an activity which is forbidden in that member state.

# Ethics in research data management

## Ownership of data / results (EU projects)

- **Data/results are owned** by the institution that generate them

If

- Two or more institutions own results jointly → jointly generated data
- Or it is impossible to establish the respective contribution of each institution or separate them.

### Written Joint Ownership Agreement (JOA)

to ensure compliance with obligations for each institution

- Each joint may grant non-exclusive license to third parties to exploit the jointly owned results (without any right to sub-license)
- The institutes must indicate the owner(s) of the data/results in the final periodic report.
- Inform 45 days in advance.



Contact [grants office UniBE](#), [Bern University Legal Services Office](#)

# Ethics in research data management

## National Institute of Health (NIH)

- New NIH Policy on Data Management and Sharing (effective January 25, 2023)
- Grants NIH Data Policy ([Link](#))



! Data should be made as widely and freely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data. NIH expects the timely release and sharing of data to be **no later than the acceptance for publication of the main findings from the final dataset.**

[https://grants.nih.gov/grants/policy/data\\_sharing/data\\_sharing\\_guidance.htm#goals](https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#goals)

# Ethics in research data management

## Swiss National Science Foundation (SNSF)

### ✓ Dos

- Obtain permissions from ethics commissions and committees latest in parallel with project evaluation
- Explain how sensitive data will be anonymised or pseudonymised. Obligation to anonymize data whenever possible.
- Use secure storage space (e.g. locked room)
- Use secure databases (e.g., RedCap)
- Share anonymised data using a FAIR research data repository, share metadata openly under CC0
- Collect only data needed for the purpose of your study

### ✗ Don'ts

- Do not share pseudonymised data openly → data protection regulations still apply
- Do not apply CC0 license to sensitive data
- Do not share sensitive data via Dropbox or Onedrive
- Do not upload any sensitive data on campus storage or campus cloud
- Do not store ID numbers and personal information at the same place

# Ethics in research data management

## Support at the UniBE. IT-Security



Basics in [Information security and data protection \(ISDP\)](#)

Contact for legal requirements and paperwork (ISDS analysis): [IT department](#) (Beatrice Hirschi)



IT-Security Workshops and presentations ([Link](#))

E-Mail: [helpdesk@id.unibe.ch](mailto:helpdesk@id.unibe.ch)

# Ethics in research data management

## Support. Where to store at the UniBE?

Use Case / Costs	Campus Storage (NAS LTS)	Campus Cloud	Ubelix (HPC)	OneDrive (Public)	Backup and Archiver
File Sharing (internal)	x	x	x	x	—
File Sharing (external)	—	x	—	x	—
Personal Data	Only when encrypted	Only when encrypted	—	Only when encrypted (not recommended)	—
Data Size	250 GB – 200 TB	from 100 GB <a href="#">costs</a>	5TB - 500TB	Quota from 5TB	unlimited
Back-up	x	x	—	—	x
Long-term	x	—	—	—	x
Costs	CHF 0.25 per GB/Year	+ 500GB: CHF200/Year + 1000GB: CHF400/Year	CHF 60.- per TB/Year	—	CHF 0.05/GB, if > 200GB

Note: Updated 07.09.2021



# Ethics in research data management

## Support at the UniBE. Legal advice

### [Bern University Legal Services Office:](#)

- Legal advice, Contracts and regulations
- Legal collection / regulations

### [Recht & Compliance Inselspital](#)

E-Mail: [studienvertrag@insel.ch](mailto:studienvertrag@insel.ch)

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##### **Legal Services Office of the University of Bern**

Hochschulstrasse 4  
3012 Bern

#### INFORMATION

##### **Judith Wittwer**

Phone **+41 31 684 51 19**  
[judith.wittwer@rechtsdiens...](mailto:judith.wittwer@rechtsdiens...)

# Ethics in research data management

## Support at the UniBE. Research data management



- Data management plan review
  - [Submit](#) online or via [E-Mail](#)
- Research data management trainings and courses
  - [Website link](#)
  - [Aktuell](#)

[Data Management Plan Review](#)

# Ethics in research data management

## Useful links, references



<https://pixabay.com/photos/search/?pagi=3&cat=computer&>

# Ethics in research data management

## References and useful links

- [Good clinical practice ICH-GCP E6\(R2\)](#)
- Training and resources in research ethics evaluation → [Elearning Trree.org](#)
- Clinical Trial Unit UniBE: [Training/Courses](#)
- RedCap database for clinical studies ([Link](#))
- Handbook for good clinical research practice (GCP) [WHO](#)
- [General Consent](#) for clinical research in Switzerland
- [Guidance](#) and [IC examples](#) by UK Data Service
- Protocols and [Informed Consent NIH](#)
- The [current NIH Data Sharing policy](#), in effect since 2003, remains in effect until January 25, 2023.

**NEWS:** New NIH Policy on [Data Management and Sharing](#) (effective January 25, 2023)



# Ethics in research data management

## Ethics tools

Ethics [RRI Tool](#)

Law [Tool](#)

[Amnesia tool](#) for sensitive data is a GDPR compliant high accuracy data anonymization.

[Qualiservice](#) the data service center for archiving and sharing qualitative research data in the social sciences

More info about tools [here](#)

# Ethics in research data management

## Data protection and legislation



- [Data protection office of the Canton of Bern](#) ([KDSG](#), DE & FR)
- [Federal Act on Data Protection \(1992/2019\)](#)
- Other legislations may apply when working with study participants from
  - other cantons Human Research Act, [EN](#), [DE](#), [IT](#), [FR](#)
  - other countries, especially Europe ([GDPR](#))
- Some countries' data protection legislations are recognized as equivalent to Switzerland's: Check [this site](#) → List of countries



# Ethics in research data management

## Ethics committees links

### Ethics commissions at the UniBE

[Faculty of Human Sciences](#)



[Faculty of Business,](#)

[Economics and Social Sciences](#)



[Animal Welfare Office](#)

Ordinance on Animal Protection (OPAn, SR 455.1, Articles 129 and 129a)

### Cantonal Ethics Committees

[Ethics committee of Canton of Bern](#)

(KEK) - for clinical research or research using biological material or health-related data.



[Swissmedic](#) – for the authorisation and supervision of therapeutic products.

# Ethics in research data management

## Anonymisation

### Before anonymisation

Name	Age	Sex	Income	Postcode
Martin Müller	51	m	79'000	3001
Andrea Sommer	21	f	55'000	3013
Dominik Fischer	44	m	102'000	3012
Arnold Furrer	65	m	40'000	3001
Simone Meier	38	f	67'000	3011

### After anonymisation

Name	Age	Sex	Income	Postcode
*	41-60	m	79'000	30**
*	21-40	f	55'000	30**
*	41-60	m	102'000	30**
*	*	*	*	30**
*	21-40	f	67'000	30**

# Ethics in research data management

## Pseudonymisation

Before pseudonymisation

Name	Age	Sex	Income	Postcode
Martin Müller	51	m	79'000	3001
Andrea Sommer	20	f	55'000	3013
Dominik Fischer	44	m	102'000	3012
Arnold Furrer	75	m	40'000	3001

After pseudonymisation

Name	Age	Sex	Income	Postcode
1	41-60	m	79'000	30**
2	21-40	f	55'000	30**
3	41-60	m	102'000	30**
4	*	*	*	30**



Pseudonymised data ≠ anonymised data → Data protection regulations apply

# Ethics in research data management

## Questions?



Thank you  
for your attention

Bern University Library, Open Science Team  
[openscience@ub.unibe.ch](mailto:openscience@ub.unibe.ch)

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<sup>b</sup>  
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BERN

